

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe each cover fiber being spaced from an adjacent cover fiber with a center-to-center distance of at least twice the cover fiber diameter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-6, 8, 10-14, 20, 22 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. (4,946,467) in view of Hill et al. (6,045,571), and further in view of Muller et al. (4,345,339). Ohi et al. disclose the invention substantially as claimed. Ohi et al. disclose, in the figures and in col. 3, line 45 to col. 4, line 35, a suture strand with core including a plurality of core fibers made of a fibrous first material (e.g., polyester) and a cover surrounding the core, where the cover is made of a fibrous second material (e.g., silk), where the core fibers are arranged in a twisted bundle, where the cover fibers are arranged to form a woven annular band, where the first material has a high tensile strength material, where the core fibers comprises a bundle of filaments of the first material, where the cover fibers comprises a bundle of filaments of the second material, where each of the core fibers is substantially circular in cross section. However, Ohi et al. do not disclose a first material that comprises a high molecular, high tenacity material or polyethylene; where the second material is a polymeric material selected from the group consisting of PET, polyester, coated urethanes, and mixtures thereof; where the second material is substantially opaque, where the first material is substantially transparent, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers, and where the plurality of cover fibers are arranged to form a loosely woven annular braid with cover fibers distanced from each other as claimed.

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Hill et al. teach, in figures 3 and 3A and in col. 7, line 17 to col. 9, line 15, a first material with a high molecular weight, high tenacity material (e.g., polyolefins according to col. 7, lines 33-38; or polyethylene in blends according to col. 8, line 28-40); a second material that is a polymeric material selected from the group as claimed (e.g., PET), and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. It would have been a matter of design choice to choose a first material with a high molecular weight, high tenacity material; a second material that is a polymeric material selected from the group as claimed, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. Such choices would be dependent upon the desired size, strength, flexibility, bioabsorbability, and hand for a suture strand. And depending on the choices of materials for the first and second materials, it would be a matter of design choice to apply a substantially opaque or transparent material. The choices would be dependent upon the type of material, the thickness of material, and the desired appearance of the suture. In short, it has been held to be within the general skill of a worker in the art to select known materials (whether for the core and/or the cover of a suture strand) on the basis of their suitability for the intended use.

Hill et al. further teach, in col. 2, line 50 to col. 3, line 27; that the denier, pick count, number of fibers, and weave pattern of the cover may vary according to several factors. Denier, pick count, number of fibers, and weave pattern directly affect or are related to the looseness of the cover's braid and the distance between cover fibers.

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Thus, it would have been a matter of obvious design choice to weave the cover's braid as claimed. The choice of how loosely to weave the cover's braid would be dependent upon the desired diameter of the cover and the desired overall denier, strength and flexibility of the suture strand.

Ohi et al. also do not disclose that the second material has a lower coefficient of friction than the first material. However, Hill et al. teach, in col. 9, lines 31-54 that the second material of the cover is lubricated or coated, or that the second material could be a lubricious polymer (e.g., fluoropolymers). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to lubricate or coat the second material, or apply a lubricious polymer as the second material, so that it has a lower coefficient of friction than the first material of the core. A lower coefficient of friction in the material of the cover would render the suture strand to be more abrasion-resistant as it is being applied for stitching or in an artificial tendon or ligament. Moreover, the low-friction filaments of the cover would be enabled to slip over one another when the suture strand is tied into a knot and thereby more evenly distribute any loading between filaments (as taught by patent application 09/159,025, incorporated by reference in Hill et al.).

Furthermore, Ohi et al. or Ohi et al. in view of Hill et al. do not disclose that the core includes an outer ring comprising a plurality of core fibers surrounding a sub-core comprising the twisted bundle, where the outer ring is arranged to form a woven annular braid. Muller teaches, at least in figure 2 and in col. 3, lines 29-68; a suture strand including, inter alia, a core comprising a sub-core (2 or 2 and 3) and an outer ring (4)

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comprising a plurality of core fibers surrounding the sub-core and arranged to form a woven annular braid. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Muller et al., to include an outer ring, as claimed, in the core of the suture strand of Ohi et al. in view of Hill et al. Such a modification would prevent or reduce abrasion between the core and the cover, as well as absorb stresses produced by longitudinal displacement of the fibers of the core with respect to each other and to the cover.

5. Claims 23-29, 34, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. in view of Hill et al. and Muller et al., and further in view of Dunn et al. (4,731,084). Ohi et al. in view of Hill et al. and Muller et al. disclose the invention substantially as claimed. The combination discloses a suture strand including, inter alia, a core comprising a core with a first plurality of core fibers forming the sub-core and a second plurality of core fibers forming the outer ring.

Ohi et al. or Ohi et al. in view of Hill et al., however, do not disclose that each cover fiber is substantially circular in cross-section, that each cover fiber is spaced from an adjacent cover fiber a center-to-center distance of at least twice the cover fiber diameter. These references also do not disclose a second diameter of the second plurality of core fibers is smaller than a first diameter of the first plurality of core fibers, and that the cover fibers have a substantially circular cross-section and a third diameter smaller than the second diameter. Also, these references do not disclose that the first, high strength, high tenacity material has a greater tensile strength than the second material. Dunn et al. teach, in col. 4, lines 1-27, a suture strand comprising a core of

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high strength, high tenacity material (e.g., polyolefins) and having a fiber tensile strength greater than or equal to 50,000 psi, which is greater than the tensile strength of the cover material (C-FLEX, tensile strength of about 2300 psi). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view Dunn et al., to apply a first material in the core of Ohi et al. in view of Hill et al. and Muller et al. that has a greater tensile strength than the second material of the cover. Such a first material could withstand the primary loading upon the suture strand with less risk of premature breakage. Muller et al. also teach, in the figures and in col. 3, line 40 to col. 4, line 9, that the diameters of fibers (of substantially circular cross-section) decrease as the diameters are measured from the core to the outer cover, while the spacing between fibers at the cover may vary. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the suture strand of Ohi et al. in view of Hill et al. or Hill et al. and Dunn et al., so that the core fibers and the cover fibers are configured and sized as claimed, and so that the covers fibers are spaced as claimed. Such modifications would ensure a suture strand having improved bending elasticity for manipulation and tying.

Response to Amendment

6. Applicant's arguments with respect to claims 1, 3-6, 8, 10-14, 20, 22-29 and 34-38 have been considered but are not persuasive. As restated above, Hill et al., whose teachings were used to modify the suture strand of Ohi et al., teach that a cover's fibers may be woven into a braid, whether loosely or not, according to a user's desired

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performance characteristics for the suture strand--characteristics including, for example, size, denier, strength, and flexibility.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

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